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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/696,362	10/30/2003	Edward W. Merrill	00952-8081	6751
90628 7590 05/13/2010 Massachusetts General Hospital The General Hospital Corporation Perkins Cole LLP 607 Fourteenth Street, NW Washington, DC 20005				
EXAMINER BERMAN, SUSAN W				
ART UNIT		PAPER NUMBER		
1796				
NOTIFICATION DATE		DELIVERY MODE		
05/13/2010		ELECTRONIC		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary

Application No.

10/696,362

Applicant(s)

MERRILL ET AL.

Examiner

/Susan W. Berman/

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03-15-2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 124-129 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 124-129 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-649)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

Response to Arguments

Applicant's arguments filed 03-15-2010 have been fully considered but they are not persuasive. See the previous discussions of these issues in the Office Actions mailed 1/14/2007, 09-07-2007, 12-12-2006, 07-24-2008 and 09-14-2009.

Applicant argues that a method of heating and irradiation that comprises heating before irradiation and irradiation before heating is inherently disclosed because the use of a van der Graaff generator is disclosed and one skilled in the art would recognize that repetitions of the recited steps are necessary to obtain a desired radiation dose. This argument is not persuasive for the following reasons. With respect to applicant's arguments about continued heating when a sample is outside the e beam, this feature is not disclosed with any specificity in the instant specification. Nor is heating prior to each irradiation dose or irradiation after each irradiation dose disclosed with any specificity in the instant specification as filed. If applicant intended to claim such a process, the process should have been clearly described in the specification as filed. There is no recognition noted that the process as now claimed was disclosed as the inventive concept in the specification as originally filed. The dictates of the MPEP with respect to a claim term having no antecedent basis in the disclosure does not apply to recitation of process steps that have no antecedent basis in the original disclosure. Applicant states that the examiner considers the process as continued heating and cooling after each pass of irradiation. The examiner disagrees. What the examiner considers is that the process being argued is not clearly described within the specification. Applicant's allegations of what is inherent to the disclosure are unpersuasive. Since Dijkstra et al are also familiar with a van der Graaff generator, then the

disclosure of Dijkstra et al also inherently discloses repetitions during the irradiation process to achieve a desired radiation dose.

With respect to whether Hyon et al is prior art, applicant continues to argue that sections 10 and 11 of the Declaration of Merrill et al filed 06-08-2009 state reduction to practice of a method wherein UHMWPE is irradiated and subsequently melted before January 20, 1995. However, the Declaration in section 10 states that Cold-irradiation and Subsequent Melting is disclosed in US Serial No. 08/726,313 filed 10-02-1996. The statement "b" "crosslink as solid, melt, recrystallize" under "Basic Motivation in Exhibit 1 is a statement of intent to explore but not evidence of a reduction to practice.

Applicant argues that the examiner has not properly construed the Declaration of record. The Declarations of record have been previously discussed and the examiner's conclusions are already of record. Applicant's argument that Hyon et al is not prior art is unpersuasive for reasons of record.

With respect to the rejection of claims over Dijkstra et al: Claim 124 recites heating to a "temperature above the melting point of the UHMWPE to about 230⁰C". Claim 127 recites heating to a "temperature from above the melting point of the UHMWPE to about 300⁰C". The 200⁰C temperature taught by Dijkstra is within each of the ranges recited in the claims. Thus the process taught by Dijkstra is a process that anticipates a process within the instantly claimed ranges. Dijkstra clearly teaches the process steps set forth in the instant claims, i.e., providing UHMWPE, heating the UHMWPE to a temperature within the instantly claimed range and irradiating the UHMWPE.

Claim Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

It is noted that instant claims 124-126 are entitled to the 02-13-1996 filing date of US 5,879,400 because this parent patent discloses the method of melt irradiation (MIR). The instant claim language in 127-129 sets forth the IR-SM processes first disclosed in SN 08/726,313, but not disclosed in US '400, and also encompasses the MIR process disclosed in US '400. Therefore, the effective filing date for instant claims 127-129 is considered to be 10-02-1996, the filing date of application SN 08/726,313, which discloses WIR-SM and CIR-SM methods as well as the "MIR" method.

Claims 124-129 are rejected under 35 U.S.C. 102(b) as being anticipated by Dijkstra et al, in the article "Crosslinking of Ultra-high Molecular Weight Polyethylene in the Melt by Means of Electron Beam Irradiation" published May, 1989. Dijkstra et al disclose a process for crosslinking UHMWPE in the melt comprising heating a perform in a nitrogen atmosphere at 200 °C and crosslinking with electron beams. See "experimental" on page 866, Table 1. With respect to claims 124-126, Dijkstra et al clearly teach heating to a temperature above the melting point of the UHMWPE to about 230°C, since 200°C is specifically taught. With respect to claims 127-129, the claims can be interpreted as requiring irradiating the perform after heating the perform. Therefor, Dijkstra et al anticipate the process set forth in claims 127-129 wherein the heating is performed before the irradiation. Since Dijkstra et al disclose process steps corresponding to those set forth in the instant claims, the process steps would be expected to

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provide a perform from which bearings having improved mechanical properties and increased wear resistance are to be fabricated, as set forth in the instant claims to define the future intended use of the process of treating the preform.

Claims 127-129 are rejected under 35 U.S.C. 102(e) as being anticipated by Hyon et al (6,168,626, having an effective filing date of May 06, 1996). Hyon et al disclose a method for producing UHMWPE for an artificial joint comprising irradiating UHMWPE with a low dose of radiation followed by compression-deformation after melting at a high temperature around the melting point and then cooling and solidifying. Table 2 appears to show that the samples treated according to the disclosed process have an increased tensile strength and an increased Young's modulus. With respect to claim 128, Hyon et al disclose temperatures around or not less than the melting point, preferably 160-220 °C (column 4, lines 4-16). Thus, claim 128 is anticipated by the teaching of Hyon et al to employ a temperature from the melting point minus 50°C to the melting point plus 80°C, which temperatures, including 160-220°C preferred by Hyon et al, would be within the range of 145 to 300°C set forth in the claim. With respect to claim 129, Hyon et al teach a preferable dose 0.01 to 5.0 MR (column 3, lines 62-65). Thus the process disclosed by Hyon et al anticipates the process of instant claim 129 wherein the gamma radiation dose is about 1 Mrad to 5.0 Mrad.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 1010 (Fed.

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Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 124-127 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 124-129, 131-134 of copending parent Application No. 10/197209. Although the conflicting claims are not identical, they are not patentably distinct from each other because the processes set forth in the corresponding claims overlap wherein the heating is at a temperature above the melting point to about 300°C and the time period is from about 5 minutes to about 3 hours or a time period of 5 minutes to about 24 hours and the polyethylene is UHMWPE. The processes set forth in the dependent claims also overlap with respect to temperature, radiation dose and intended properties. Thus the limitations of the process set forth in the instant claims are obvious variants of the limitations set forth in the claims of A.N. 10/197209.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 124-127 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 124-125, 130 and 143-146 of copending parent Application No. 09/764,445. Although the conflicting claims are not

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identical, they are not patentably distinct from each other because the processes set forth in the corresponding claims overlap wherein the heating is at a temperature above the melting point and below the decomposition temperature for a time period from about 5 minutes to about 3 hours. The processes set forth in the dependent claims also overlap with respect to temperature, radiation dose and intended properties. The polyethylene recited in the claims of A.N. '445 encompasses the UHMWPE recited in the instant claims. Claims 124, 125 and 130 suggest instant claim 127. Claim 143 suggests instant claim 124. Thus species within the instant claims are obvious from the limitations set forth in the claims of A.N. 09/764,445.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to /Susan W. Berman/ whose telephone number is 571 272 1067. The examiner can normally be reached on M-F 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Seidleck can be reached on 571 272 1078. The fax phone number for the organization where this application or proceeding is assigned is 571 273 8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SB
5/7/2010

/Susan W Berman/
Primary Examiner
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